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09/602,251	06/23/2000	David T. Carrott	DSD9906US3	9356

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EXAMINER	
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2621	13

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Please find below and/or attached an Office communication concerning this application or proceeding.

PTO-90C (Rev. 10/03)

Office Action Summary	Application No. 09/602,251	Applicant(s) CARROTT ET AL.
	Examiner Hussein Akhavannik	Art Unit 2621

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10,19,21,22 and 24-28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10,19,21,22 and 24-28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *03 July 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

1. The amendment to the specification overcomes the Examiner's objections cited in paragraph 6 of the previous office action (now Paper No. 7).

2. The amendments to claims 1 and 19 overcome the Examiner's 35 U.S.C. 112, first paragraph rejection of these claims cited in paragraph 8 of the previous office action (now Paper No. 7).

3. The amendments to claim 1 overcome the Examiner's 35 U.S.C. 112, second paragraph rejection of claims 6, 7, 9, and 10 cited in paragraph 10 of the previous office action (now Paper No. 7).

Response to Arguments

4. Applicant's arguments with respect to claim 1 on page 13, line 10 to page 15, line 17 of the Remarks (now paper No. 10) have been considered but are moot in view of the new ground(s) of rejection.

The Applicant alleges that Yanagita et al do not disclose that the composite image emphasizes the temporal image differences in synthetic colors on page 15, lines 19-30 of the Remarks (now Paper No. 10). The Examiner respectfully disagrees. Yanagita et al explicitly explain in column 13, lines 19-25 that hue (color) is changed depending on the magnitude of the difference image pixel.

Applicant's arguments with respect to claim 3 on page 16, lines 20-31 of the Remarks (now paper No. 10) have been considered but are moot in view of the new ground(s) of rejection.

The Applicant alleges that Mitchell et al do not disclose three-dimensional imaging on page 17, lines 21-30 of the Remarks (now Paper No. 10). The Examiner respectfully disagrees. Mitchell et al do explicitly explain producing three dimensional mammography images in column 10, lines 16-22. The Applicant explains that three-dimensional data is preferred only if available on page 5, lines 12-13 of the specification. Therefore, it would have been an obvious matter of design choice to modify the system of Kalend et al and Yanagita et al by having at least one of the historical and rescanned ROI images be three-dimensional, since the Applicant has not disclosed that having three-dimensional historical and rescanned ROI images solves any stated problem or is for any particular purpose and it appears that the registration and comparison system of Kalend et al and Yanagita et al would perform equally as well with either two-dimensional or three-dimensional images.

Applicant's arguments with respect to claim 19 on page 19, line 8 to page 21, line 15 of the Remarks (now paper No. 10) have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 2-4 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Referring to claim 2, "said step of spatially adjusting" is indefinite as amended claim has two steps of spatially adjusting, so it is not clear which step claim 2 is further defining.

Claims 3-4 are indefinite for depending from an indefinite antecedent base claim.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. Claims 1-3, 5-6, 9-10, and 24-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kalend et al (U.S. Patent No. 5,784,431) in view of Yanagita et al (U.S. Patent No. 5,982,953).

Referring to claim 1,

i. Obtaining a first image of a region of tissue is illustrated by Kalend et al in figure 1, reference number 1, wherein a first image is obtained (simulation image DSIS as explained in column 4, lines 26-32).

ii. Obtaining pathological feature data for the region of tissue is explained by Kalend et al in column 7, lines 50-65 by the rectangular region.

iii. Obtaining a second image of a region of tissue at a first level of resolution is illustrated by Kalend et al in figure 1, reference number 1', wherein a second image is obtained (portal image DPIS as explained in column 4, lines 33-42).

iv. Digitally storing the first and second images as digitized first and second images is illustrated by Kalend et al in figure 1, reference number 29.

v. Spatially adjusting at least one of the first and second digitized images to spatially register the images so that corresponding features in both images are mapped to

corresponding positions is illustrated by Kalend et al in figure 1, reference number 33. Kalend et al explain warping the simulation image by rotation and translation toward the portal image, thereby performing the coarse alignment in column 5, lines 33-66.

vi. Correlating the pathological feature data with the second image to define a historical region-of-interest (ROI) in the second image is explained by Kalend et al in column 8, lines 3-26, wherein rectangular region (corresponding to the pathological feature) is correlated (motion flow that is determined to cause pixels on one image to flow into alignment with corresponding pixels in the other image). The historical ROI in the portal (second) image corresponds to the rectangular region in the portal image that intersects (or corresponds to) the rectangular region in the simulation image.

vii. Rescanning the defined ROI using a second level of resolution higher than the first level of resolution to obtain a third image is illustrated by Kalend et al in figure 9, reference number 166. Kalend et al explain performing the correlation at several levels of resolution until an upper limit of resolution has been reached in column 7, line 66 to column 8, line 26.

viii. Spatially adjusting at least one of the historical and rescanned ROI images to spatially register the ROI images so that corresponding features in both images are mapped to corresponding positions is explained by Kalend et al in column 8, lines 27-28 and column 6, lines 1-24, corresponding to the fine alignment. The parameters for the fine alignment are determining by the rescanned ROI at the upper limit of resolution.

ix. Creating from the historical and rescanned ROI images a composite image which visually emphasizes temporal differences between the ROI images, thereby visually

emphasizing historical change between the historical and rescanned ROI images is not explicitly explained by Kalend et al. Kalend et al do explain spatially adjusting the simulation image towards the portal image in order to accurately compare the two images in the abstract. However, Kalend et al do not explicitly explain creating a composite image that visually emphasizes temporal differences between the images. Yanagita et al illustrate such a composite image in figure 2, reference number S8. Yanagita et al explain that two registered images are subtracted from each other in order to create a subtraction image in column 9, lines 12-22. Yanagita et al explain that the composite image clearly shows the change in a portion of a radiograph image to a doctor, thereby improving the efficiency of medical diagnosis in column 2, lines 3-16. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to create a composite image to visually emphasize historical change between the historical and rescanned ROI images, as suggested by Yanagita et al, in the system of Kalend et al because both system are directed towards registering and comparing two radiographic images and Yanagita et al explains that a composite image increases the efficiency of medical diagnosis from the comparison.

Referring to claim 2,

i. Determining a coordinate transformation which produces at least a pre-determined degree of correlation between the first and second images is explained by Kalend et al in column 5, line 65 to column 6, line 24, wherein the variables for the affine transformation are determined.

ii. Applying the coordinate transformation to at least one of the first and second digitized images to align the images is illustrated by Kalend et al in figure 1 by the fine alignment 35 performed on the first (simulation) image.

Referring to claim 3,

i. Applying coordinate transformations of scale, position, and rotation to one of the first and second digitized images, to obtain a plurality of corresponding adjusted images is explained by Kalend et al in column 5, line 65 to column 6, line 24 by the affine transformation which alters the scale (deformation due to breathing), position (translation), and rotation.

ii. Cross-correlating the adjusted images with one of the first and second digitized images to produce a correlation output corresponds to claim 2i. At each resolution, the simulation image and the portal image are correlated.

iii. Selecting a coordinate transformation which produces at least a defined correlation output from its corresponding adjusted image is explained by Kalend et al in column 8, lines 22-28, wherein the variables for the affine transformation are selected from the highest level of resolution.

Referring to claim 5, recording the composite image for archiving is illustrated by Yanagita et al in figure 1 by the image memory (7), which can store the output images of the image processing section (5).

Referring to claim 6, storing the composite image on a computer recordable medium is illustrated by Yanagita et al in figure 1 by the image memory (7), which stores the output images of the image processing section and can be read by a computer.

Referring to claim 9,

i. Comparing an image intensity at a location in the historical ROI image with a respective intensity at a corresponding location in the rescanned ROI image is explained by Yanagita et al in column 9, lines 12-16. The pixel values are representative of the intensity at a location in the first image and corresponding location in the second image.

ii. Determining a temporal difference image value based upon the temporal difference between the image intensity at the location in the historical ROI image and the respective intensity at the corresponding location in the rescanned ROI image is explained by Yanagita et al in column 9, lines 12-16. The corresponding pixel values of the first and second image are subtracted from each other to create a subtraction image.

Referring to claim 10, the composite image visually emphasizing temporal image differences by representing various regions of the composite image in synthetic colors, based upon image differences between the first and second images is explained by Yanagita et al in column 13, lines 19-25. By changing the hue depending on the difference value, the difference values would be represented by different colors.

Referring to claim 24, the pathological feature data being obtained by manually analyzing the first image data is explained by Kalend et al in column 1, lines 54-63, wherein anatomical landmarks are manually determined.

Referring to claim 25, the pathological feature data corresponds to predetermined image shapes or characteristics retrieved from a pathological image library is explained by Kalend et al in column 7, lines 54-57.

Referring to claim 26, the pathological feature data being obtained by automated analysis of the first image is explained by Kalend et al in column 2, lines 36-55, wherein the registration is performed automatically.

9. Claims 7 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kalend et al in view of Yanagita et al, and further in view of Wang (U.S. Patent No. 6,477,262).

Referring to claim 7, printing an image based upon the composite image is not explicitly explained by Kalend et al or Yanagita et al. However, Wang does illustrate printing an image in figure 1 by the laser film printer (580). Printing an image in order to archive it is extremely well known in the art. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to print an image based on the composite image, as suggested by Wang, in the system of Kalend et al and Yanagita et al because printing is well-known to archive images.

Referring to claim 27, the second image being obtained using ultrasonic imaging is not explicitly explained by Kalend et al or Yanagita et al. However, Wang does explain acquiring mammography images using ultrasound in column 7, lines 18-44. Using ultrasonic imaging systems to acquire images of biological tissue is well known in the art and could be substituted for the imaging system of Kalend et al and Yanagita et al. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to obtain a second image using ultrasonic imaging, as suggested by Wang, in the system of Kalend et al and Yanagita et al because ultrasonic imaging is an extremely well method of acquiring radiographic images.

10. Claims 8 and 28 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kalend et al in view of Yanagita et al, and further in view of Mitchell et al (U.S. Patent No. 5,433,202).

Referring to claim 8, at least one of the historical and rescanned ROI images being three-dimensional is not explicitly explained by Kalend et al or Yanagita et al. However, Mitchell et al do explain producing three dimensional mammography images in column 10, lines 16-22. The Applicant explains that three-dimensional data is preferred only if available on page 5, lines 12-13 of the specification. Therefore, it would have been an obvious matter of design choice to modify the system of Kalend et al and Yanagita et al by having at least one of the historical and rescanned ROI images be three-dimensional, since the Applicant has not disclosed that having three-dimensional historical and rescanned ROI images solves any stated problem or is for any particular purpose and it appears that the registration and comparison system of Kalend et al and Yanagita et al would perform equally as well with either two-dimensional or three-dimensional images.

Referring to claim 28, both of the historical and rescanned ROIs being three-dimensional volume regions that are aligned by registration in three dimensions is not explicitly explained by Kalend et al or Yanagita et al. However, Mitchell et al do explain producing three dimensional mammography images in column 10, lines 16-22, which would inherently require alignment in three dimensions. The Applicant explains that three-dimensional data is preferred only if available on page 5, lines 12-13 of the specification. Therefore, it would have been an obvious matter of design choice to modify the system of Kalend et al and Yanagita et al by having both of the historical and rescanned ROIs be three-dimensional volume regions, since the Applicant has not disclosed that having three-dimensional historical and rescanned ROI regions solves any

stated problem or is for any particular purpose and it appears that the registration and comparison system of Kalend et al and Yanagita et al would perform equally as well with either two-dimensional or three-dimensional regions.

11. Claims 4, 19, and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kalend et al in view of Yanagita et al, and further in view of Trezza (U.S. Patent No. 6,538,791).

Referring to claim 4,

i. Inputting the first and second images to an optical correlator is not explicitly explained by Kalend et al or Yanagita et al. However, Trezza illustrates inputting two images to an optical correlator in figure 1. The first image is the sample image (28) and the second image is the reference image (37). Trezza explains that an optical correlator would be extremely important in the medical field, especially in to determine the results of mammography because of high speed in column 1, lines 52-67. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to input a first and second image to an optical correlator, as suggested by Trezza, because the cross correlation would be performed at a higher speed.

ii. Reading the correlation output from the output of the optical correlator is not explicitly explained by Kalend et al or Yanagita et al. However, Trezza illustrates reading the correlation from an optical correlator in figure 1 by the output correlation (30).

Referring to claim 19,

i. Receiving a first image of a region of tissue corresponds to claim 1i.

ii. Obtaining pathological feature data for the region of tissue corresponds to claim 1ii.

iii. Obtaining a second image of the region of tissue using a first level of resolution corresponds to claim 1iii.

iv. Registering the first and second images by controlling an optical correlator to find a position of correlation between the first and second images is not explicitly explained by Kalend et al or Yanagita et al. Kalend et al do explain registering first and second images through digital means, corresponding to claim 1v. However, Trezza does illustrate using an optical correlator to find the correlation between two images in figure 1. Trezza explains that an optical correlator would be extremely important in the medical field, especially in to determine the results of mammography because of high speed in column 1, lines 52-67. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to register a first and second image in the system of Kalend et al and Yanagita et al using an optical correlator, as suggested by Trezza, because the cross correlation would be performed at a higher speed.

v. Correlating the pathological feature data with the second image to define a historical region-of-interest (ROI) in the second image corresponds to claim 1vi.

vi. Rescanning the defined ROI using a second level of resolution higher than the first level of resolution to obtain a third image corresponds to claim 1vii.

vii. Registering the historical and rescanned ROI images by controlling an optical correlator to find a position of correlation between the historical and rescanned ROI images corresponds to claim 1viii.

viii. Derive a composite image from the historical and rescanned ROI images corresponds to claim 1ix.

ix. Emphasizing the temporal differences in the composite image corresponds to claim 10.

x. An optical correlator coupled to the image processor and arranged perform the correlations is illustrated by Trezza in figure 1, corresponds to section iv of this claim.

Referring to claim 21, permitting a user to view the composite image on a display is illustrated by Yanagita et al in figure 1 as the image display section (6).

12. Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kalend et al in view of Yanagita et al and Trezza, and further in view of Wang.

Referring to claim 22, an ultrasonic imaging system arranged to communicate ultrasonographic image data to the image processor to provide at least one of the first and second image is not explicitly explained by Kalend et al or Yanagita et al or Trezza. However, Wang does explain acquiring mammography images using ultrasound in column 7, lines 18-44. Using ultrasonic imaging systems to acquire images of biological tissue is well known in the art and could be substituted for the imaging system of Kalend et al, Yanagita et al, and Trezza. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to obtain the first and second images using ultrasonic imaging, as suggested by Wang, in the system of Kalend et al, Yanagita et al, and Trezza because ultrasonic imaging is an extremely well method of acquiring radiographic images.

Conclusion

13. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Xu et al (U.S. Patent No. 6,363,163) – To exhibit cross correlation of a pathological feature in multiple images as illustrated in figure 6c.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hussein Akhavannik whose telephone number is (703)306-4049. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Leo H. Boudreau can be reached on (703)305-4706. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Hussein Akhavannik H.A.
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